K033263

OCT 3 1 2003

Section 5

510(K) Summary

Submitted by:	Track Corporation, Inc.
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	Spring Lake, MI 49456
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	e-mail:
Contact:	Jon Emery
Date:	09/20/02
Name of Device:	K-Tech 2 Power Tilt Seating System
Trade Name:	K-Tech 2 Power Tilt Seating System
Common Name:	Power Tilt-in-Space Seating System, Center of Gravity, Power Tilt in Space.
Classification Name:	Wheelchair, Powered
Product Code:	ITI
Regulation Number:	890.3860
Type:	Traditional

Substantial Equivalence:

K981837:	Motion Concepts, TRx-CG Center of Gravity Shifting Power Tilt
K972564:	Tiltmaster Center of Gravity Power Tilt System

Description:

The Track Corporation K-Tech Power Tilt Seating System is an aftermarket, center of gravity design power tilt in space system for power wheelchairs. The K-Tech 2 is designed to be able to be installed in the field by qualified dealerships on to most commercially available power wheelchairs appropriate for power seating accommodation. The standard system configuration consists of two sets of steel tracks, an inner and outer set. This track configuration has been used in the automotive industry very successfully for many years, under more rigorous conditions than wheelchairs experience. The outer tracks of the K-Tech 2 are attached to the power wheelchair via mounting hardware that is designed to interface to each specific power chair.

The outside tracks also provide the guide tracks for the inside tracks to tilt and slide forward, creating the center of gravity movement. The aluminum seat pan and the inside tracks support the back support uprights. The K-Tech 2 utilizes an automotive seat adjuster motor manufactured by Fasco and has a maximum load capacity of 500 pounds. The Fasco motor has an integrated overload protection to protect the motor from current overload and over use by the end user. The tilt drive assembly found integrated into the back end of the inner tracks follows a steel leadscrew attached inside of each of the outer tracks. This creates a dual screw drive which is much more efficient and does not put the users weight directly on the tilt adjuster, unlike on the actuators that are found on the predicate device(s). This is a significant improvement in durability and safety in power wheelchair seating. If the motor should ever fail, the tilt drive assembly will not change its relationship to the leadscrew. The end user is protected from the system either falling backward or free falling back down to the neutral seated position due to motor failure. An additional benefit of using the tilt drive assembly and ball screw is the tilting of the system is achieved by the movement of the screw guide on the ball screw. This allows the device to tilt and slide forward without exerting great stress and opposing forces on the frame, which exist on the predicate devices and all other available tilt power seating systems. Over time, these opposing forces cause undue strain on the frame, leading to possible serious failure. The K-Tech 2 is activated with a standard low amp toggle switch. It can also be activated by running the system through commercially available optional specialty controls for the end user that does not have the ability to activate a toggle switch. As the toggle switch is activated, the K-Tech 2 will begin to tilt and simultaneously move forward to center the end user's weight over the power chair base, maintaining stability of the base and end user while tilted.

The K-Tech has a standard infinitely adjustable tilt range of zero to 55 degrees and custom tilt ranges are available. There is a micro-switch

attached to the frame, which is activated once the end user tilts past 20 degrees, locking out the driving capabilities of the power chair for safety.

Intended Use:

The K-Tech 2 is appropriate for use by individuals that use a power wheelchair for mobility and require positioning changes without the aid of an attendant. These positioning changes are needed for, but not limited to:

- Comfort for increased sitting tolerance
- Positioning to enable upper body stability
- Pressure relief or reduction by shifting the end user's body weight from the buttocks to the back

Track Corporation makes no claims as to the therapeutic effectiveness of this device. Our only claims relate to the ability of the device to provide safe and reliable change in positioning capability on the equipment that it is installed.

The above indications are identical to those of Motion Concepts K981837 and Mechanical Application Designs K972564.

Technological Characteristics:

The Track Corporation K-Tech 2 Power Tilt Seating System is a battery powered motorized seating system for power wheelchairs. It is designed as an aftermarket seating system that can be mounted onto a variety of currently available power wheelchairs that are suitable to accommodate power seating. The K-Tech 2 incorporates two sets of tracks that allow the system to be configured to accommodate a wide range of end user sizes from very small individuals up to the bariatric end user using the same sets of tracks. The K-Tech 2 incorporates the use of an automotive seat adjuster motor to tilt the system, creating a "dual drive," by turning the Tilt Drive Assembly on the right and left leadscrew. If the motor should ever fail, the Tilt Drive Assembly will not change its relationship to the leadscrew (no back drive), hence the end user is protected from the system either falling backward or free falling back down to the neutral seated position due to motor failure. This provides both efficiency and safety not found on the predicate devices or on other available power seating. This also enables the system to be tilted without any opposing forces on the frame, as is the case with the predicate devices.

Performance Data:

Cycle/Durability Test:: Completed 18,000 tilt cycles satisfactorily without failure. Results are found in appendix D.

The K-Tech 2 in its standard configuration meets the applicable requirements specified in ISO 7176.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2003

Track Corporation, Inc.
C/o Mr. Ned Devine
Entela, Inc
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K033263
Trade/Device Name: K-Tech 2 Power Tilt Seating System
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: October 24, 2003
Received: October 27, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-1308. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Applicant: Track Corporation
510(k) Number (if known): TBD K033263
Device Name: K-Tech 2 Power Tilt Seating System
Indications For Use:

The K-Tech 2 is appropriate for use by individuals that use a power wheelchair for mobility and require positioning changes without the aid of an attendant. These positioning changes are needed for, but not limited to:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033263